K122979

JUN 0 4 2013

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

VIDAS® Lyme IgM

A. Submitter Information

Submitter's Name:	bioMérieux SA
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Date of Preparation:	August 2012

B. Device Name

Trade Name:	VIDAS® Lyme IgM
Common Name:	Lyme IgM Assay
Classification Name:	21 CFR 866.3830 – Treponema pallidum treponemal test reagents

C. Predicate Device Name

Trade Name: Platelia™ Lyme IgM

D. Device Description

The VIDAS Lyme IgM assay principle combines a 2-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA) (see User's Manual).
The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and predispensed in the sealed reagent strips.
All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.
After a preliminary wash step and a sample dilution step, the antibodies to *B. burgdorferi* present in the specimen will bind to the B. burgdorferi specific recombinant proteins coating the interior of the SPR.
Unbound sample components are washed away. Anti-human IgM antibodies conjugated with alkaline phosphatase, will attach to the immunocomplex bound to the SPR wall.
A final wash step removes unbound conjugate. During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the quantity of anti-B. burgdorferi IgM antibody present in the sample.
At the end of the VIDAS Lyme IgM assay, results are automatically calculated by the instrument. A test value is generated and a report is printed.

E. Intended Use

The VIDAS Lyme IgM (LYM) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgM antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgM positive and equivocal specimens should be further tested with a Western Blot IgM assay to obtain supportive evidence of infection with *B. burgdorferi*.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the assays is presented in the table below.

Item	VIDAS® Lyme IgM (LYM) Assay	Platelia™ Lyme IgM (K081362)
Intended Use	The VIDAS Lyme IgM (LYM) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgM antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgM positive and equivocal specimens should be further tested with a Western Blot IgM assay to obtain supportive evidence of infection with *B. burgdorferi*.	The Platelia™ Lyme IgM Test is a qualitative test intended for use in the presumptive detection of human IgM antibodies to *Borrelia burgdorferi* in human serum or plasma (K3 EDTA, sodium heparin or sodium citrate). The EIA system should be used to test serum or plasma from patients with a history and symptoms of infection with *Borrelia burgdorferi*. All positive and equivocal specimens should be re-tested with a specific, second-tier test such as Western-Blot. Positive second-tier results are supportive evidence of infection with *Borrelia burgdorferi*. The diagnosis of Lyme disease should be made based on history and symptoms (such as erythema migrans), and other laboratory data, in addition to the presence of antibodies to *Borrelia burgdorferi*. Negative results (either first- or second-tier) should not be used to exclude Lyme disease.
Specimen	Serum or plasma	Serum or plasma
Analyte	IgM antibodies to *Borrelia burgdorferi*	IgM antibodies to *Borrelia burgdorferi*
Automated	Yes	No
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Enzyme immunoassay (EIA)

G. Nonclinical Tests

A summary of the non-clinical results is presented below.

Precision

For the precision study, 4 serum samples were tested in duplicate in 40 different runs (2 runs per day over 20 days) with 2 reagent lots at 1 site (n = 80). The precision was calculated following the recommendations of the CLSI® document EP5-A2. The total precision data in the table reflect the 80 values generated per sample for Site 1 and takes into account replicate, run, day, calibration, and lot as potential sources of variation. The total precision for controls include within-day, between-days and between-calibration variability and is lot specific.

Panel Member	N	Mean Index	Within-run		Within-day		Between-days		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Sample 1	80	0.19	0.01	3.9	0.01	2.7	0.00	0.0	0.01	5.2
Sample 2	80	0.27	0.01	4.7	0.01	2.8	0.00	1.4	0.02	9.1
Sample 3	80	0.38	0.01	2.6	0.01	3.0	0.00	0.3	0.02	4.7
Sample 4	80	1.31	0.03	2.1	0.02	1.6	0.01	0.9	0.09	6.9
Positive Control	40	0.74	NA	NA	0.04	5.3	0.00	0.0	0.07	10.1
Negative Control	40	0.00	NA	NA	0.00	0.0	0.00	0.0	0.00	0.0

Reproducibility

For reproducibility, 4 serum samples were tested in duplicate in 40 different runs (2 runs per day over 20 days) with 2 reagent lots at 3 sites (n =240). The reproducibility was calculated following the recommendations of the CLSI® document EP5-A2. The total reproducibility data in the table reflects the 240 values generated per sample for all sites and takes into account replicate, run, day, calibration, lot, and site as potential sources of variation. Out of the 240 total values, 2 Low Positives (Sample 3) gave an equivocal value (< 0.32). The total reproducibility for controls include within-day, between-days, between-calibration and between-site variability and is lot specific.

Panel Member	N	Mean Index	Within-run		Within-day		Between-days		Between-site		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Sample 1	240	0.19	0.01	3.5	0.00	2.1	0.00	1.0	0.00	0.0	0.01	6.3
Sample 2	240	0.26	0.01	4.3	0.01	2.7	0.00	0.7	0.01	2.1	0.02	7.8

Panel Member	N	Mean Index	Within-run		Within-day		Between-days		Between-site		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Sample 3	240	0.37	0.01	3.1	0.01	2.1	0.00	0.0	0.00	0.0	0.02	6.2
Sample 4	240	1.26	0.03	2.5	0.02	1.9	0.01	0.4	0.00	0.0	0.12	9.4
Positive Control	120	0.72	NA	NA	0.03	4.6	0.00	0.0	0.00	0.0	0.09	12.1
Negative Control	120	0.00	NA	NA	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0

Interfering Substances

Specimen-related interference

Interferences were studied according to the recommendations of CLSI® document EP7-A2. None of the following factors have been found to significantly influence this assay:

- hemolysis (after spiking samples with hemoglobin: 5 g/L (monomer)),
- lipemia (after spiking samples with lipids: 30 g/L equivalent in triglycerides),
- bilirubinemia (after spiking samples with bilirubin: 0.3 g/L),
- human albumin (after spiking samples with albumin up to 60 g/L).

It is recommended not to use samples that are clearly hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

Exogenous Interferents: Following the recommendations of CLSI® document EP7-A2, the potential interferences with 15 commonly used drugs were studied. No interference was observed at the concentration tested.

Drug	Concentration tested	Drug	Concentration tested
Acetylsalicylic acid	3.62 mmol/L	Ibuprofen	2425 µmol/L
Amoxicillin	206 µmol/L	Minocycline	4.1 µmol/L
Azithromycin	34 µmol/L	Penicillin G	240 000 U/L
Betamethasone	8.31 µmol/L	Penicillin Phenoxymethyl	30 000 U/L
Ceftriaxone	1460 µmol/L	Prednisolone	8.31 µmol/L
Cefuroxime axetil	1416 µmol/L	Roxithromycin	15.3 µmol/L
Doxycycline hyclate	16.1 µmol/L	Tetracyclines	67.5 µmol/L
Erythromycin	22.2 µmol/L		

H. Clinical Testing

Sensitivity testing

202 retrospective samples from patients meeting a case definition of LD and confirmed positive for *B. Burgdorferi* infection were run on the VIDAS Lyme IgM assay and the predicate Lyme IgM assay.
For both the VIDAS Lyme IgM and the predicate test, equivocal results were considered as positive for the evaluation. The following results were obtained:

Stage	N	VIDAS Lyme IgM % Sensitivity *	Predicate Lyme IgM % Sensitivity *	Difference in proportions
Stage I (early localized, single lesion) 1 – 30 days	119	52.1 (62/119) 95% CI [42.8 – 61.3]%	54.6 (65/119) 95% CI [45.2 - 63.8]%	-2.5% 95% CI [(-15.2)% – (10.2)%]
Stage II (early disseminated, multiple lesions) 1 – 30 days	62	91.9 (57/62) 95% CI [82.2 - 97.3]%	91.9 (57/62) 95% CI [82.2 – 97.3]%	0.0% 95% CI [(-9.6)% – (9.6)%]
Stage III (late disseminated)	21	76.2 (16/21) 95% CI [52.8 - 91.8]%	61.9 (13/21) 95% CI [38.4 – 81.9]%	14.3% 95% CI [(-13.3)% – (41.9)%]
All stages	202	66.8 (135/202) 95% CI [59.9 – 73.3]%	66.8 (135/202) 95% CI [59.9 – 73.3]%	0.0% 95% CI [(-9.2)% – (9.2)%]

* includes positive and equivocal results.

Method Comparison

A prospective study was performed on 975 fresh or frozen prospectively collected sera submitted for routine Lyme disease testing from an endemic area of the United States. Testing was performed in three laboratories.
At each laboratory, the samples were tested in parallel using a commercially available Lyme IgM EIA method (predicate) and the VIDAS Lyme IgM assay. Positive % Agreement (PPA) is calculated for the positives and equivocals together since the 2-tier testing does not make a distinction and calls for both of them to be tested by Western Blot. Combined results from the three sites are shown below:

N = 975	Predicate Lyme IgM		
VIDAS Lyme IgM	**Positive**	**Equivocal**	**Negative**
Positive	71	10	32
Equivocal	15	11	55
Negative	50	53	678
Total	136	74	765
Positive % Agreement 95% CI	51.0% (107/210) [44.0 - 57.9]%		
Negative % Agreement 95% CI	88.6% (678/765) [86.2 - 90.8]%		

Second-Tier Testing: In accordance with the CDC recommendations for use of a 2-tier Lyme disease testing scheme, the VIDAS Lyme IgM positive and equivocal results and the predicate Lyme IgM positive and equivocal results were confirmed using a commercially available Lyme IgM Western Blot method.
The percent agreement between VIDAS and predicate Lyme IgM positives (1st tier PPA) and the percent agreement between VIDAS–predicate–Western Blot IgM positives and Predicate–Western Blot IgM positives (2nd tier PPA) are shown below.

	1st Tier + or ±	IgM Western	
		Pos.	Neg.
Predicate IgM	210	104	106
VIDAS IgM	194	95	93*
VIDAS IgM and Predicate IgM	107	84	23

*, Western Blot results were not available for 6 of the positive or equivocal samples by VIDAS Lyme IgM assay.

Agreement results:
1st Tier PPA = 51.0% (107/210), 95% CI=[44.0% - 57.9%]
2nd Tier PPA= 80.8% (84/104), 95% CI=[72.2% - 87.2%]

Concordance with IgM Western Blot:
Predicate device: 49.5% (104/210)
VIDAS Lyme IgM: 49.0% (95/194)

Analytical Specificity

100 sera from apparently healthy subjects from an endemic population (New York) and 100 sera from a non-endemic population (Texas) with no known history of Lyme disease were run on the VIDAS Lyme IgM assay and the predicate Lyme IgM assay. The following results were obtained:

	VIDAS		Predicate	
	Positivity*	**Negativity**	**Positivity***	**Negativity**
Endemic	12.0%	88.0%	19.0%	81.0%
Non-Endemic	14.0%	86.0%	3.0%	97.0%

* Includes positives and equivocals.

CDC Reference Panel

The following information is from a serum panel obtained from the CDC and tested using the VIDAS Lyme IgM kit. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

Time from onset	VIDAS Lyme IgM			Western blot IgM		
	Positive or equivocal	Negative	Agreement with clinical status	Positive	Negative	Agreement with clinical status
Normals	1	4	80.0 % (4/5)	0	5	100.0 % (5/5)
< 1 month	3	2	60.0 % (3/5)	3	2	60.0 % (3/5)
1 – 2 months	5	1	83.3 % (5/6)	5	1	83.3 % (5/6)
3- 12 months	12	4	75.0 % (12/16)	7	9	43.8 % (7/16)
> 1 year	3	4	42.9 % (3/7)	3	4	42.9 % (3/7)
Total	24	15	69.2% (27/39)	18	21	59.0 % (23/39)

Cross-Reactivity

Cross-reactivity is based on the study of samples that are negative with the test being evaluated and positive for the potentially interfering disease. The results of the samples tested according to the disease are shown in the table below:

Infection or Diagnosis	N	VIDAS Lyme IgM Equivocal or positive results	% Cross-reactivity
Anti Nuclear Antibodies	60	3	5.00
C Reactive Protein	61	4	6.55
Cytomegalovirus	34	6	17.64
Epstein Barr Virus	65	7	10.76
Helicobacter pylori	143	10	6.99
Hepatitis A Virus	153	22	14.37
Herpes Simplex Virus	98	15	15.30
Human Immunodeficiency Virus	20	7	35.00
Human Anti-mouse Antibodies	31	2	6.45
Leptospirosis	216	22	10.18
Measles	38	5	13.15
Mumps	46	2	4.34
Rheumatoid Factor	61	5	8.19
Rickettsiosis	112	6	5.35
Rubella	19	2	10.52
Syphilis	270	25	9.25
Systemic Lupus Erythematosus	28	2	7.14
Toxoplasmosis	26	5	19.23
Varicella Zoster Virus	58	4	6.89

The effect of Babesiosis, Erhlichiosis and Rocky Mountain spotted fever pathologies on the VIDAS Lyme IgM performance is not known.

I. Conclusion

The results from the nonclinical and clinical studies submitted in this premarket notification are complete and demonstrate that the VIDAS® Lyme IgM is substantially equivalent to the predicate device identified in Item C of this summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

bioMerieux SA
c/o Catherine FRITSCH
Regulatory Affairs Director
5 rue des Aqueducs
69290 Craponne, France

June 4, 2013

Re: K122979
Trade/Device Name: VIDAS® Lyme IgM
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: May 6, 2013
Received: May 7, 2013

Dear Ms. FRITSCH:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122979

Device Name: VIDAS® Lyme IgM

Indications For Use:

The VIDAS Lyme IgM (LYM) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgM antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi.* All VIDAS Lyme IgM positive and equivocal specimens should be further tested with a Western Blot IgM assay to obtain supportive evidence of infection with *B. burgdorferi.*

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) K122979

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)